

**REMARKS**

Claims 2-5 and 7, and 9-34 are pending in the application. Claims 9, 16, 17, and 26 are independent claims.

Claims 17-22, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,399,316 to Yamada.

Yamada discloses a reaction vessel 10 with a base member 11, spacers 12, 13 spaced apart forming a groove 14, and a cover 17 having a U-shaped notched portion 15 having a width larger than that of the groove 14. See, Column 4 lines 60-67. The notched portion, base member 11 and spacers 12 and 13 define an injection region 22. See, Column 5 lines 9-10.

It is proposed that claim 17 be amended to clarify the structure of the device's detection element as well as its cover. Specifically, claim 17 as amended recites that the cover's detection element has a reagent-impregnated membrane and that the cover has opposite first and second edges. The second edge of the cover faces the first end of the membrane. Support for the amendment is found in the specification as filed and particularly at page 11 lines 4-5 and in Figures 1A-1G. The amendment is properly entered here as it does not add new matter and puts the application in condition for allowance of better form for appeal.

It is submitted that in light of the above amendment, Yamada fails to disclose or suggest a device as recited in claim 17. It is submitted that there is no description or suggestion in Yamada of a membrane, let alone a reagent-impregnated membrane having an end facing an edge of a cover. Yamada is devoid of description or suggestion of a device comprising a reagent-impregnated membrane.

In addition, claim 17 as amended recites that the second edge of the cover faces the first end of the membrane. Not one of the figures of Yamada discloses an edge of a cover facing a detection element, let alone a reagent-impregnated membrane. In fact, as shown in Figure 1, the edges of the cover 17 face away from any specific affinity material or insoluble material positioned in the reaction region (21). Accordingly, Yamada cannot be said to anticipate the device of amended claim 17.

Accordingly, there is simply no disclosure or suggestion in Yamada of a device comprising "a carrier, a detection element having a reagent-impregnated membrane with opposite first and second ends, and a cover having a surface and

opposite first and second edges, the second edge facing the first end of the detection element, and the cover cooperating with a surface of the carrier and the detection element to form a capillary-active channel, the channel having a sample application opening defined by at least one edge and extending at least from the opening to the second end of the membrane, and wherein at least one notch in the form of a partial groove is positioned at the at least one edge of the sample application opening of the channel so that one side of the edge of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as recited by amended claim 17. As such, claim 17 as amended is not anticipated and is believed to be patentable over Yamada.

Moreover, it is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is noted that the teaching or suggestions, as well as the expectation of success, must come from the prior art and not applicant's disclosure. With this in mind it becomes apparent that Yamada fairly considered for all that it teaches, does not contain the requisite suggestion or incentive that would have motivated the skilled artisan to modify said reference to meet the limitations of amended claim 17. Claims 18-22, 24, and 25 depend from amended claim 17.

It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 102(b) and 103(a). Entry of the amendments leading to reconsideration of the rejection of the claims and withdrawal of the rejection is respectfully requested.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,399,316 to Yamada in view of U.S. Patent No. 4,439,526 to Columbus. Yamada has been discussed above with reference to amended claim 17. Claim 19 depends from claim 17.

Columbus et al. discloses a device having an exterior surface for receipt of liquid deposited and a wall means interior of the surface for transporting liquid by capillary attraction along a passage. See, Column 2, lines 29-33. Columbus fails to cure the inadequacies of Yamada in relation to amended claim 17. Claim 19 depends from amended claim 17.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection of the claims and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,399,316 to Yamada in view of U.S. Patent No. 6,238,624 to Heller et al. Yamada has been discussed above with reference to amended claim 17. Claim 19 depends from claim 17.

Heller et al. disclose a self-addressable, self-assembling microelectronic device designed and fabricated to actively carry out and control multi-step and multiplex molecular biological reactions in microscopic formats. See, the abstract. Heller et al. fail to cure the inadequacies of Yamada in relation to amended claim 17. Claim 23 depends from amended claim 17.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejections of the claims and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

Claims 2-5, 9-14, 16, 26-31, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,399,316 to Yamada in view of U.S. Patent No. 5,942,102 to Hodges et al.

It is proposed that claims 9 and 16 be amended to clarify the structure of the device's cover as well as its position relative to the detection element. Specifically, claims 9 and 16 as amended recite that the cover has opposite first and second edges. The second edge of the cover faces the first end of the detection element. Support for the amendment is found in the specification as filed and particularly in Figures 1A-1G. The amendments are properly entered here as they do not add new matter and put the application in condition for allowance of better form for appeal.

It is submitted that the resulting combination or modification proffered by the rejection fails to show or suggest a device as recited in claim 9 and 16 in light of the amendments and/or the accompanying remarks.

The Examiner's statement that "Yamada fails to disclose the at least one notch having a width less than that of the channel" (Page 8, third paragraph) is acknowledged. Further, it is submitted that Yamada teaches away from such a device. Yamada at most discloses a large notched portion that exposes both a gap as well as its surrounding spacers.

In order to highlight the differences between the claimed device and the reaction vessel of Yamada, the Examiner's attention is first directed to Column 5 lines 36-39 of Yamada, where it teaches that, "Since a portion exposed from the cover 17 is large, this portion can store an excessive portion of the amount or reagent or the like which exceeds the capacity of the reaction region 21."

Applicant's ignored Yamada's teaching of a large notch and taught instead in the specification at page 5, first paragraph, that the selection of the dimensions of the notch ensures that the liquid drop comes into contact with the capillary active zone with very high probability, independent of the exact position of the dosing. Yamada's large notch simply does not provide this assurance of contact with the capillary channel and requires that steps be taken to provide for direct contact. Specifically, Yamada instructs at Column 6 lines 64-68, that "A sample solution . . . is dripped in the injection region 22 with a pipette". As such, Yamada not only fails to teach the device of the present claims, but it works to lead one skilled in the art away from it.

Differences between the claimed element and the device of Yamada also exist by Yamada's teaching of its groove (14). Yamada at most teaches that its groove (14) extends along the base (1) between the spacers (12, 13). Such a structure is in direct contrast to the device of claims 9 and 16 as amended. Claims 9 and 16 each recite that the cover has a second edge that faces the detection element. Not one of the figures of Yamada discloses an edge of a cover facing a detection element. In fact, as shown in Figure 1, the edges of the cover (17) face away from any specific affinity material or insoluble material positioned in the reaction region (21).

It is respectfully submitted that the secondary reference to Hodges et al. fails to cure the above-stated inadequacies of Yamada. Hodges et al. is devoid of description or suggestion of a device comprising a notch having a width less than that of the channel that is positioned at the at least one edge of the sample application opening of the channel. Hodges et al. at most discloses a cell having a wall 10 that notched at 9 to provide a solution to be admitted to the cell or to be drawn in by wicking or capillary action and to allow air to escape. (Column 5, lines 3-6). Further,

Hodges et al. is devoid of description or suggestion of the claimed relative positioning between the cover and the detection element.

The combination of Yamada and Hodges et al. cannot be motivated by hindsight in view of Applicant's specification. There is no motivation in the cited references to replace the large notched portion (15) that extends over spacers (12, 13) as taught by Yamada with the notches (9) of Hodges et al., which themselves form the path to the cell. It is submitted that the combination of the teachings of Yamada and Hodges et al. would lead to a reaction vessel in which the notched portion had the same width as the groove in its injection region. This is clearly not what is claimed in the presently amended claims 9 and 16.

In light of the above, it is submitted that Yamada and Hodges et al. when taken as a whole, fail either alone or in combination to disclose or suggest a device comprising "a carrier, a detection element having opposite first and second ends, and a cover having a surface and first and second opposite edges, the second edge facing the detection element, the cover cooperating with a surface of the carrier and the detection element to form a capillary-active channel, the channel having a sample application opening defined by at least one edge, the channel extending at least from the opening to the second end of the detection element, and wherein at least one notch in the form of a partial groove and having a width less than that of the channel is positioned at the at least one edge of the sample application opening of the channel so that one side of the edge of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as required by amended claim 9. Claims 2-5 and 10-14 depend from amended claim 9.

It is further submitted that in light of the above, that Yamada and Hodges et al. when taken as a whole, fail either alone or in combination to disclose or suggest a method comprising the steps of "providing a device that comprises a carrier, a detection element having opposite first and second ends, and a cover having a surface and opposite first and second edges, the second edge facing the detection element, the cover cooperating with a surface of the carrier and the detection element to form a capillary-active channel having a sample application opening defined by at least one edge, the channel extending at least from the opening to the second end of the detection element, and wherein at least one notch in the form of a partial groove and having a width less than that of the channel is positioned at the at least one edge of the

sample application opening of the channel so that one side of the edge of the sample application opening is at least partially interrupted by the at least one notch and the surface opposite to the at least one notch facing the channel is exposed and contacting the edge of the sample application opening adjacent to the notch with the liquid sample so that the liquid sample is transported by capillary forces into the channel", as required by amended claim 16.

Claim 26 recites a device comprising a channel having a sample application opening wherein at least one notch having a width less than the channel's width is positioned at the at least one edge of the sample application opening. As discussed above, Yamada at most discloses a large notched portion that exposes both a gap as well as its surrounding spacers.

Applicant's ignored Yamada's teaching of a large notch extending across spacers and discovered that the recited notch ensures contact of the liquid drop with the capillary active zone with high probability, independent of the exact position of the dosing. Yamada's large notch simply does not provide this assurance of contact with the capillary channel and requires that steps be taken to provide for direct contact. Specifically, Yamada instructs at Column 6 lines 64-68, that "A sample solution . . . is dripped in the injection region 22 with a pipette". As such, Yamada not only fails to teach the device of the present claims, but it works to lead one skilled in the art away from it.

It is respectfully submitted that the secondary reference to Hedges et al. fails to cure the above-stated inadequacies of Yamada. Hedges et al. is devoid of description or suggestion of a device comprising a notch having a width less than that of the channel that is positioned at the at least one edge of the sample application opening of the channel. Hedges et al. at most discloses a cell having a wall 10 that is notched at 9 to provide a solution to be admitted to the cell or to be drawn in by wicking or capillary action and to allow air to escape. (Column 5, lines 3-6).

The combination of Yamada and Hedges et al. cannot be motivated by hindsight in view of Applicant's specification. There is no motivation in the cited references to replace the large notched portion (15) that extends over spacers (12, 13) as taught by Yamada with the notches (9) of Hedges et al., which themselves form the path to the cell.

In light of the above, it is submitted that Yamada and Hedges et al. when taken as a whole, fail either alone or in combination to disclose or suggest a device

comprising "a carrier, and a cover having a surface that cooperates with a surface of the carrier to form a capillary-active channel, the channel having a sample application opening defined by at least one edge and wherein at least one notch in the form of a partial groove and having a width less than the channel's width is positioned at the at least one edge of the sample application opening of the channel so that one side of the edge of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as required by claim 26. Claims 27-28, 30, 31, 33, and 34 depend from claim 26.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Entry of the amendments, reconsideration of the rejections of the claims, and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

Claims 2 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,399,316 to Yamada in view of U.S. Patent No. 5,942,102 to Hodges et al. as applied to claims 9 and 26 and further in view of U.S. Patent No. 4,439,526 to Columbus. Yamada and Hodges et al. have been discussed above with reference to amended claim 9 and claim 26.

Columbus et al. discloses a device having an exterior surface for receipt of liquid deposited and a wall means interior of the surface for transporting liquid by capillary attraction along a passage. See, Column 2, lines 29-33. Columbus fails to cure the inadequacies of Yamada in relation to amended claim 9 and claim 26. Claim 2 depends from claim 9 and claim 28 depends from claim 26.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejections of the claims and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

Claims 7, 15, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,399,316 to Yamada in view of U.S. Patent No.

5,942,102 to Hodges et al. as applied to claims 9 and 26 and further in view of U.S. Patent No. 6,238,624 to Heller et al. Yamada and Hodges et al. have been discussed above with reference to amended claim 9 and claim 26.

Heller et al. disclose a self-addressable, self-assembling microelectronic device designed and fabricated to actively carry out and control multi-step and multiplex molecular biological reactions in microscopic formats. See, the abstract. Heller et al. fail to cure the inadequacies of Yamada in relation to amended claim 9 and claim 26. Claims 7 and 15 depend from amended claim 9 and claim 32 depends from claim 26.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejections of the claims and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

This application is deemed to be in condition for allowance and as such is respectfully requested. In addition, if necessary, it is requested that this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and fees be charged to Deposit Account No. 50-0877 (with reference to RDID 0043 US).

Respectfully submitted,

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